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510(k) Summary of Safety and Effectiveness

Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer

Submitted by:
Abbott Laboratories
Hospital Products Division
D-389. Bldg. J-45
200 Abbott Park Road
Abbott Park, IL 60064

Date Prepared:
May 22, 2002

Contact:
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Associate Director
Regulatory Affairs
Phone: (847) 937-8473
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Name/Classification of Device:
Single-function, preprogrammed diagnostic computer
Class II, Medical Device
21 CFR 870.1435
Product Code: DXG
FDA Panel: Cardiovascular

Proposed Device:
Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer
List Number: 56711

Predicate Devices:
Abbott Model 3000 Opticath Computer (SvO2/TdCO), K853018
Abbott Continuous Cardiac Output System, renamed the Qvue, (CCO/TdCO), K932414

Proposed Device Description:
The proposed Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer is based on modifications to existing Abbott devices and combines the functions into a single unit. The proposed device will be capable of measuring the following parameters:

1. CCO, Continuous Cardiac Output
2. SO2, Saturation of oxygen in the blood
3. Body core temperature
4. TDCO, Standard bolus thermal-dilution cardiac output
5. Calculation of other hemodynamic parameters

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Proposed Device Description: (cont'd)

The Q2™ Plus system consists of the Q2 monitor and it is to be used with the following medical devices: an Abbott SvO_2/CCO catheter, Abbott Optical Module, an Oximetrix Printer and various connecting cables. Patient data is derived from an indwelling cardiac catheter.

The Q2™ Plus unit is the size of a desktop computer with a monochrome CRT, front panel keypad (for user input), and various connectors for the catheter, optical module, and serial (RS-232) lines. The instrument has a single computer and various peripheral and special purpose controller boards.

The proposed instrument consists of two subsystems, the Interface Control Processor (ICP) and the Core Control Processor (CCP) which are connected by a serial data link.

Special Controls (Section 514)

There are no requirements or special controls under Section 514 of the Federal Food, Drug, and Cosmetic Act that are applicable to the Q2™ Plus.

Intended Use:

The Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer has the following indications for use.

- It is intended for deriving and monitoring hemodynamic and cardiac parameters in patients with pre-existing central line access.
- It monitors cardiac output, body core temperature and blood oxygen saturation. These and other calculated hemodynamic values are displayed and may be communicated to other external monitoring systems.
- It is intended to be used in medical and surgical intensive care units, operating rooms, trauma and accident emergency units, coronary and intensive care units and cardiac catheterization labs.

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Comparative Analysis:

The Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer has been demonstrated to be as safe and effective as the predicate devices for their intended use. The subject device will have the same indications for use as the predicate devices. The proposed device incorporates the functions of the predicate devices into a single unit.

Functional/Safety Testing:

The Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer has successfully undergone bench and functional testing as well as software verification and validation, electrical safety and environmental testing.

Discussions and Conclusions from Bench Testing:

Data regarding the functional performance of the proposed Q2™ Plus has been generated and reviewed. The results of testing conducted to validate and verify the design modifications demonstrate acceptable performance of the device. These results do not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Abbott Laboratories
c/o Mr. Ned E. Devine, Jr.
Program Manager III
Entela, Inc.
3033 Madison Avenue SE
Grand Rapids, MI 49548

Re: K021874
Trade Name: Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer
Regulation Number: 21 CFR 870.1435 and 870.2700
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer and Oximeter
Regulatory Class: Class II (two)
Product Code: DXG and DQA
Dated: June 27, 2002
Received: June 28, 2002

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

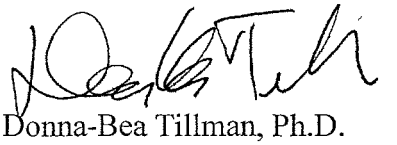
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K021874

Device Name: Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer

Indications For Use:

The Abbott Q2™ Plus SO2/Continuous Cardiac Output Computer has the following indications for use:

It is intended for deriving and monitoring hemodynamic and cardiac parameters in patients with pre-existing central line access.

It monitors cardiac output, body core temperature and blood oxygen saturation. These and other calculated hemodynamic values are displayed and may be communicated to other external monitoring systems.

It is intended to be used in medical and surgical intensive care units, operating rooms, trauma and accident emergency units, coronary and intensive care units and cardiac catheterization laboratories.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The_Counter Use_____

(per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021874